REMARKS

In the final Office Action mailed December 14, 2004, pending claims 1-16 were rejected. Claim 2 is cancelled herein and claims 1 and 8 are amended. Reconsideration of claims 1 and 3-16 presently pending in light of the amendments and the following remarks is respectfully requested.

A. Amended Independent Claim 1 and Dependent Claims 3-7 Are Distinguishable Over a Combination of *Hernandez* and *Granja*.

The rejection of claims 1 and 3-7 under 35 U.S.C. § 103(a) over *Hernandez* (U.S. Patent No. 6,235,795) in view of *Granja* (U.S. Patent No. 6,235,795) for reasons of record in the Office Action of March 24, 2004 is respectfully traversed. The rejection is premised upon contentions that *Hernandez* discloses "mixtures of higher primary alcohols made from beeswax generically overlapping applicants' useful in treating ulcers and as anti-inflammatory agents as well as their production by extraction" and notes that Hernandez "differs from the instant invention in that micronizing and use in treating cholesterol and inflammatory disorders is not disclosed." The Office Action concludes that "it would have been *prima facie* obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of the cited references, to make applicants' compositions and to expect them to be useful in treating cholesterol and inflammatory disorders"

A *prima facie* case of obviousness has not been established. First, the prior art reference or combination of references must teach or suggest all the limitations of the claims (*In re Vaeck*, 947 F.2d 488 20 USPQ2d 1438 (Fed. Cir. 1991; emphasis added). Also, the prior art relied upon must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references (*In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). Lastly, the proposed modification of the prior art must have had a reasonable expectation of success (*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991; emphasis added).

Here, *prima facie* obviousness has not been established for at least the following reasons: (1) no prior art as been cited for the proposition that micronization is generally known in the pharmaceutical arts; (2) even if well known, no art has been cited showing a motivation to combine the references showing that

there is some incentive to combine the micronization technique in the present case; (3) the precise compositional profile of the mixture of claim 1 is not taught in either *Granja* or *Hernandez*; and (4) there has been shown no motivation to combine *Granja* and *Hernandez* to obtain all features of the present invention, as is done in the Office Action.

In the absence of a particular reference teaching micronization in a manner relevant to the technology of the present invention, *prima Facie* obviousness has therefore not been established relative to amended claim 1, and so claim 1 and dependent claims 3-7 are patentably distinguishable over the art of record.

B. Amended Independent Claim 8 and Dependent Claims 9-12 Are Distinguishable Over a Combination of *Hernandez* and *Granja*.

The rejection of claims 8-12 under 35 U.S.C. § 103(a) over *Hernandez* (U.S. Patent No. 6,235,795) in view of *Granja* (U.S. Patent No. 6,235,795) for reasons of record in the Office Action of March 24, 2004 is respectfully traversed.

Here, *prima facie* obviousness has not been established for at least the following reasons: (1) the prior art does not teach a composition made according to a process in which the starting material is ground into particles prior to extraction, (2) even if this step is well known, no art has been cited showing a motivation to combine the required showing that there is some incentive to combine the particularization technique in the present case; (3) the precise compositional profile of the mixture of claim 1 is not taught in either *Granja* or *Hernandez*; and (4) there has been shown no motivation to combine *Granja* and *Hernandez* to obtain all features of the present invention, as is arbitrarily done in the Office Action.

Thus, amended claim 8 and dependent claims 9-12 are patentably distinguishable over the references of record.

C. Claims 13-16 Are Distinguishable Over a Combination of *Hernandez* and *Granja*.

Claims 13-16 each claim compositions utilizing the "consisting essentially of" transition language. Since *Hernandez* and *Granja* each describe different compositional profiles, given the unpredictability of the chemical arts, the lack of complete overlap of each of different compositional profiles of *Hernandez* and *Granja*, the inclusion of other constituents and/or constituents in different

proportions, and the lack of motivation to combine the references, the particular compositional profile recited in claims 13-16 is believed to be patentably distinguishable over the references.

More particularly, although Hernandez and Granja broadly disclose mixtures of higher primary aliphatic alcohols containing alcohols ranging from 24-34 carbons, neither reference teaches or suggests a mixture of primary aliphatic alcohols which includes, *inter alia*, a **C-20** alcohol (i.e., 1-eicosanol) **and** a **C-22** alcohol (i.e., 1-docosanol) as required in the compositions of the present invention. Since the combination of *Hernandez* and *Granja* does not teach or suggest all of the elements of claims 13-16, a *prima facie* case of obviousness has not been established.

For the reasons presented above, claims 1 and 3-16 are distinguishable over the cited references. Withdrawal of the § 103(a) rejection is respectfully requested.

D. Petition for 3-Month Extension.

A Notice of Appeal was filed March 14, 2005. Applicant hereby petitions for a 3-Month Extension, extending the due date for filing this RCE to August 15, 2005 (August 14, 2005 being a Sunday).

E. Fees and Conclusion.

The enclosed check includes payment of the large entity 3-month extension fee and the RCE filing fee. Should any additional fee or petition for extension be required, the Office is authorized to charge Deposit Account No. 50-1123. The Examiner is asked to kindly contact the undersigned by telephone should any outstanding issues remain.

Respectfully submitted,

August 15, 2005

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